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United States District Court,N.D. California.

ICU MEDICAL, INC., Plaintiff,

v.

B.BRAUN MEDICAL INC., Defendants.

No. C 01-3202 CRB.

March 14, 2005.

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ORDER RE: MOTIONS FOR SUMMARY JUDGMENT AND SCHEDULING TRIAL

BREYER, J.

***1** Plaintiff and Counterclaim Defendant ICU Medical, Inc. ("ICU") brought this suit against Defendant and Counterclaimant B.Braun Medical, Inc. ("Braun") for infringement of U.S. Patent No. 5,928,204 ("the '204 patent") and U.S. Patent No. 6,669,673 ("the '673 patent") by manufacturing and selling a specialized needleless medical connector. The patents relate to a medical valve for use in controlling the flow of fluid between two medical implements. The alleged infringing device is Braun's Ultrasite valve.

ICU and Braun cross-move for summary judgment on the issue of whether the Ultrasite valve [FN1] infringes the '673 patent. Braun also seeks summary judgment of non-infringement of both the '673 and '204 patents by the Ultrasite valve with modified piston. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

FN1. In late 2004, Braun made a modification to the Ultrasite valve by changing the molds used in manufacturing the piston component to remove an alleged "taper" in the piston skirt. The modified valve will be referred to in this Order as the Ultrasite valve with modified piston. Otherwise, the term "Ultrasite valve" will refer to both the unmodified Ultrasite valve and the Ultrasite valve with modified piston.

Having carefully considered the parties' papers, and with the benefit of oral argument on February 11, 2005, the Court hereby resolves the motions as follows:

1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

BACKGROUND

The administration of medication in hospital and medical settings routinely involves the use of connectors and adaptors for facilitating the movement of fluids (e.g., drugs and intravenous solutions) between medical implements. Since the ready passage of fluids through the connectors and adaptors is often critical to patient survival, it is important that they operate reliably and repeatedly. Both Braun and ICU are providers of needleless medical connectors.

Braun's Ultrasite valve is a needle-free, capless, swabbable valve. It contains a piston made of flexible material. When the piston is in its uncompressed state, it seals against the housing of the valve preventing fluid flow through the valve. In this state, the wall of the piston is relatively flat. When a syringe or other appropriate medical device is connected to the valve, the piston is compressed

causing the piston wall to buckle. The compressed piston no longer completely seals against the valve housing because the portion of the piston that seals against the housing is moved to a location where there are channels in the housing. When the piston is compressed, fluid can flow through the valve.

ICU is the assignee of two patents (the '673 and '204 patents) for a closed system, needleless valve device which automatically reseals after administering medication using a medical implement that directly connects with the system without the need of any intermediary needles, caps, or adaptors.

I. THE '673 PATENT

***2** Independent claim 1 reads:
A medical valve for controlling the flow of fluid between a first medical implement and a second medical implement, said valve comprising:
....
... a flexible element positioned in said cavity movable between an uncompressed position in which a portion of the flexible element bears against the wall structure near said opening and obstructs fluid flow through said valve and a compressed position in which fluid flow is permitted through said valve, said flexible element comprising a wall with an inner surface and an outer surface, the wall flexing to accommodate axial compression of said flexible element, said flexible element comprising an end fitting against a ring shaped support to assist in securing said flexible element in said cavity, said flexible element in said uncompressed position comprising a first external diameter near said opening, a second external diameter in said main portion, said second diameter being smaller than said first diameter and said third diameter, and at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered.

U.S. Patent No. 6,669,673 (issued Dec. 30, 2003). Claims 2-6 are dependent claims from claim 1.

The Court issued its claim construction order regarding the '673 patent on November 8, 2004 (the "Markman Order"). In its Markman Order, the Court determined that the term "flexible element" should be defined as "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. The flexible element must be moveable from an uncompressed position, in which the valve is closed, to a compressed position, in which "it is under axial compression from a medical implement" and "the valve is in an open state and fluid is allowed to move through it." *Id.* at 9, 7. When the flexible element is in an uncompressed position, it must "bear against the wall structure" and "obstruct[ ] fluid flow" through the valve. '673 Patent Claim 1.

II. THE '204 PATENT

Independent claim 1 reads:
A seal for use in selectively opening and closing a fluid pathway through a medical connector comprising a resilient seal element having a wall having a top end and a bottom end, said wall including at least two generally arcuate segments each having an outwardly extending portion, said segments intersecting one another and defining at least one space between where said segments intersect and a line tangential to the outwardly extending portions of both segments, and at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element.

U.S. Patent No. 5,928,204 (issued July 27, 1999). Claims 2-5 are dependent claims from claim 1.

DISCUSSION

ICU and Braun cross-move for summary judgment on the issue of whether Braun's Ultrasite valve infringes claims 1-3 and 5-6 of the '673 patent. Braun also seeks summary judgment of non-infringement by the Ultrasite valve with modified piston with regard to claims 1-6 of the '673 patent and claims 1-5 of the '204 patent. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

I. STANDARD OF REVIEW FOR SUMMARY JUDGMENT

***3** Summary judgment is appropriate when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). An issue is "genuine" only if there is sufficient evidence for a reasonable fact finder to find for the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49, 106 S.Ct. 2505, 91 L.Ed.2d

202 (1986). A fact is "material" if the fact may affect the outcome of the case. *See id.* at 248. "In considering a motion for summary judgment, the court may not weigh the evidence or make credibility determinations, and is required to draw all inferences in a light most favorable to the non-moving party." *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir.1997). A principal purpose of the summary judgment procedure is to identify and dispose of factually unsupported claims. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *See id.* at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *See id.* Once the moving party meets this initial burden, the non-moving party must go beyond the pleadings and by its own evidence "set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). The non-moving party must "identify with reasonable particularity the evidence that precludes summary judgment." *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir.1996) (quoting *Richards v. Combined Ins. Co.*, 55 F.3d 247, 251 (7th Cir.1995), and noting that it is not a district court's task "to scour the record in search of a genuine issue of triable fact"). If the non-moving party fails to make this showing, the moving party is entitled to judgment as a matter of law. *See Celotex*, 477 U.S. at 323.

II. INFRINGEMENT OF THE '673 PATENT

A patent infringement analysis involves two steps: claim construction and then applying the construed claim to the accused device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995). The first step, construing the claims to determine their meaning and scope, has been held to be purely a matter of law. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998). The second step, application of the claim to the accused device, is a fact-specific inquiry. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998) ("[I]nfringement, whether literal or under the doctrine of equivalents, is a question of fact."). If each limitation of the patent claim is found in the accused device, either literally or as a substantial equivalent, the accused device infringes that claim. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

***4** Summary judgment is appropriate in infringement suits when, drawing all reasonable inferences in favor of the non-moving party, there is no genuine issue of material fact. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed.Cir.1999). Because the relevant aspects of the accused device's structure and operation are undisputed in this case, the question of infringement collapses to one of claim construction and is particularly amenable to summary judgment. *Id.*

A. Literal Infringement

To establish literal infringement, the accused device must "contain each limitation of the claim exactly." *Litton Sys., Inc. v. Honeywell Inc.*, 140 F.3d 1449, 1454 (Fed.Cir.1998). The Court will proceed to compare the accused Ultrasite valve against all the claims and each of their limitations.

1. Claim 1 of the '673 patent

Claim 1 is the only independent claim of the '673 patent. It claims a medical valve for *controlling the flow of fluid* comprising a *flexible element* that: (1) *obstructs fluid flow* through the valve, (2) comprises *a wall flexing to accommodate axial compression* by a medical implement, (3) comprises *an end fitting against a ring shaped support,* and (4) is *tapered.* ICU asserts that Braun's Ultrasite valve satisfies each of these elements.

a. "Controlling the flow of fluid"

The Ultrasite valve plainly controls the flow of fluid from one medical implement to another. Braun's argument that its Ultrasite valve does not control fluid flow between two medical implements fails even under its own offered definition in which "control" means "to exercise restraint *or* direction over." Braun's Opposition Memorandum at 19 (quoting Random House Dictionary 442 (2d ed.1983)) (emphasis added). Removing the implement inserted into the top of the Ultrasite valve restrains the flow of fluid as the piston moves toward its uncompressed position. Inserting a medical implement opens the valve, allowing fluid to flow between that implement and another implement

connected to the other end of the valve. When the Ultrasite valve connects two medical implements, it controls the flow of fluid by restraining the fluid within the valve and directing the flow from one implement to the other.

The term "control" should not be read so narrowly as to require the regulation of any "maximum" or "minimum" fluid flow. The preferred embodiments in the '673 patent work in a similar way (as does the Ultrasite valve) to control the flow of fluid between two medical implements: inserting a syringe or other medical implement opens the valve by exposing passageways that allow fluid to flow from one implement to the other. The '673 patent does not recite a medical valve that independently starts, shuts off, slows-down, or speeds-up the flow of fluids. To accept Braun's argument would exclude the elected embodiments of the '673 prosecution, and produce a highly disfavored result for which Braun provides insufficient support. *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1381 (Fed.Cir.2004) (vacating summary judgment of non-infringement where accused infringer's claim interpretation would have excluded patent's preferred embodiment; such an interpretation is "rarely, if ever, correct.").

b. "Flexible element" that "obstructs fluid flow"

***5** Braun's Ultrasite valve also comprises a flexible element that obstructs fluid flow through the valve. In its claim construction, the Court construed the disputed claim language as follows. The term "flexible element" means "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. ICU does not assert that the entire piston assembly (including the piston component, rigid plug, and spring) constitutes the flexible element. Rather, ICU contends that only the piston component, or piston, infringes the "flexible element" limitation of claim 1.[FN2] ICU's Reply Memorandum at 4-5.

> FN2. For the purposes of this Order, the term "piston" refers to the piston component as opposed to the entire piston assembly.

The piston is clearly a flexible element under the claim language. It is made in a single molding of an elastomeric material, which allows it to flex or bend without breaking. The piston bends at several points during operation of the valve. In the uncompressed position, the lip of the piston flexes in response to radial pressure as it is squeezed into the neck of the housing. The shoulder of the piston flexes when it is pressed against the housing shoulder. The neck of the piston also flexes during insertion of the rigid plug and spring at assembly. The piston skirt flexes in response to axial pressure when it is moved into a compressed position by a medical implement.

Braun contends that the elastomeric piston is not "flexible" inside the valve because the rigid plug inserted into the neck of the piston is not flexible. The Court's construction, however, does not require that the flexible element must be bent, only that it is *capable* of being bent. Insertion of the rigid plug does not change the fact that the piston is still capable of being bent in response to pressure (e.g., radially from the rigid plug or housing wall, and axially from the medical implement), which is all the claim requires. Indeed, insertion of the rigid plug causes the piston neck to flex in response to radial pressure, and insertion of a medical implement causes the piston skirt to flex in response to axial pressure when it is moved into a compressed position.

Braun further contends that ICU's position is inconsistent with its earlier claim that the Ultrasite valve satisfies a "rigid sealing element" limitation in U.S. Patent No. 6,245,048 (the '048 patent). Claim 1 of the '048 patent recites "a rigid sealing element ... movable between a first position in which said seal prevents fluid flow and a second position in which fluid flow is permitted...." Braun's argument fails because ICU is not contending that the same features of the valve are both a "rigid sealing element" and a "flexible element." Rather, ICU refers to the stiffened lip and neck portion of the combined piston assembly as the "rigid sealing element," but only the piston component as the "flexible element." Although the Ultrasite piston assembly as a whole is rigid, the piston component remains flexible. It does not follow that a stiffened piston assembly cannot comprise a "flexible" piston which is capable of bending in response to pressure.

***6** The piston also obstructs fluid flow through the valve. In an uncompressed position, the lip of the piston bears against the housing wall and the rigid plug to create a seal that obstructs fluid from entering the valve. The piston shoulder also bears against the internal housing wall and prevents fluid from flowing through the valve. Insertion of a medical implement pushes down on the rigid plug, which moves the piston from an uncompressed position to a compressed position in which fluid is allowed to flow

through passageways in the valve.

Braun's argument that the rigid plug, not the piston, obstructs fluid flow through the valve is not supported by the evidence. In the Ultrasite valve, the fluid path is around the outside of the piston assembly, not through it. Even without the rigid plug, the piston bears against the housing wall near the valve opening and at the piston shoulder, blocking the passageways that allow fluid to flow through the valve. Although the piston component is hollow, a fluid barrier exists at the base where the piston is compressed between the luer nut and the housing wall. So even without a rigid plug, the piston obstructs fluid flow.

Moreover, Braun's contention that the piston or flexible element alone must obstruct fluid flow through the Ultrasite valve is not what the claim requires. Claim 1 is a "comprising" claim for "a medical valve ... comprising ... a flexible element ... [that] obstructs fluid flow...." A claim that incorporates the term "comprising" is "generally understood to signify that the claims do not exclude the presence in the accused apparatus ... of factors in addition to those explicitly recited." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811-12 (Fed.Cir.1999) (reversing summary judgment of non-infringement where accused device included features in addition to elements claimed in a "comprising" claim); *see also Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed.Cir.1991) (a claim "which uses the term 'comprising,' is an 'open' claim which will read on devices which add additional elements"). "The signal 'comprising' implements the general rule that absent some special circumstance or estoppel which excludes the additional factor, infringement is not avoided by the presence of elements ... in addition to those specifically recited in the claim." *Vivid Techs.*, 200 F.3d at 811.

Here, Braun cannot escape infringement by pointing to other elements in the Ultrasite valve such as the rigid plug that also obstruct fluid flow. There are no special circumstances and Braun has not pointed to anything in the '673 prosecution history that would allow it to evade the general rule that an accused infringer cannot escape infringement by pointing to elements in his device that are in addition to those elements in the claimed invention. *See id.* Braun's Ultrasite valve infringes despite the fact that the piston component is not the only element obstructing fluid flow through the valve.

c. "A wall flexing to accommodate axial compression"

*7 The Ultrasite valve also comprises a wall that flexes to accommodate axial compression. The claim recites "a flexible element ... comprising a wall ... flexing to accommodate axial compression." Braun's argument that there can be only one wall that flexes (its entirety) in the flexible element in response to axial compression is not what the claim requires. The claim describes a flexible element that comprises or includes "a wall" that flexes in response to axial compression, but may also include other parts that do not flex in response to axial pressure.[FN3] The claim should not be read to require that the entire piston must flex to accommodate axial compression. *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed.Cir.1988) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims.").

FN3. As ICU correctly notes, the use of the indefinite article "a" in an open-ended, "comprising" claim does not limit that claim to the singular. *KJC Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed.Cir.2000) ("This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.' ").

Here, the piston component is the flexible element. Inserting a syringe or other medical implement moves the piston into a compressed position and causes the piston skirt to flex in response to axial pressure. Accordingly, the piston skirt is *a wall* that flexes to accommodate axial compression of the piston, and satisfies the claim limitation.

d. "An end fitting against a ring shaped support"

Claim 1 of the '673 patent also requires that the flexible element has an "end fitting against a ring shaped support." In its claim construction, the Court found the term "ring shaped support" to be unambiguous. Markman Order at 11. In the Ultrasite valve, the piston component sits on top of the Luer nut, which makes up the bottom part of the body of the housing. Braun contends that the Luer nut presents nothing more than "a flat surface on which the piston assembly sits" and cannot constitute a

"ring shaped support." Braun's Opposition Memorandum at 20. The top surface of the Luer nut, however, is not flat. The "annular sealing ring" on the face of the Luer nut includes a concentric series of ring-shaped ridges. The piston plainly fits against a ring-shaped support, which helps to secure the piston in the housing body, and satisfies the claim limitation.

e. "At least a portion ... of the wall ... being tapered"

The final limitation of claim 1 requires that a portion of the wall of the flexible element be "tapered" between the second and third diameters. The parties agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21. ICU asserts that the skirt of the piston component in the Ultrasite valve satisfies this limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve meets the "taper" limitation. Indeed, the valve contains a slight taper along the skirt of the piston component. Braun states that the taper is a draft mold, or a well-known non-functional by-product of the manufacturing process. Nevertheless, the piston skirt gradually diminishes in width towards one end of the Ultrasite valve structure as the claim requires.

***8** Braun contends, however, that to the extent a slight mold draft on the unmodified valve could be considered a taper, Braun has now removed it from the Ultrasite product. The piston component of the newly modified valve is no longer tapered. Instead, the piston skirt consists of straight walls. The question of whether the new, modified Ultrasite valve infringes the '673 patent is considered further below.

As to the unmodified Ultrasite valve, Braun has failed to raise any material issue of fact to rebut ICU's showing that it contains each limitation of claim 1 of the '673 patent. Consequently, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 1 of the '673 patent.

2. Claim 2 of the '673 patent

Claim 2 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position near the opening must be "substantially flat." The lip of the Ultrasite valve's piston component is substantially flat. Braun contends, however, that "the end of the piston that is closest to the opening is substantially open, not flat." Braun's Opposition Memorandum at 23. But claim 2 does not require the end of the piston component to be both flat and disc-shaped as opposed to ring-shaped. Therefore, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 2 of the '673 patent.

3. Claim 3 of the '673 patent

Claim 3 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position must be "substantially flush with the opening of said cavity of said body." ICU contends that "substantially" is a modifier implying "approximately" rather than "perfect." ICU's Reply Memorandum at 12; *see also Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1368-69 (Fed.Cir.2004) (noting that the term "substantial" is a modifier implying "approximate," rather than "perfect"). But the Ultrasite valve's piston component is not even "approximately" flush with valve opening. Instead, it is recessed in the cavity of the valve near the opening. The lip of the piston component sits beneath the rigid plug, which in turn sits below the top surface of the valve opening. Therefore, the Court finds that the Ultrasite valve does not literally infringe claim 3 of the '673 patent.

4. Claim 5 of the '673 patent

Claim 5 of the '673 patent incorporates all the limitations in claim 1 and adds that the flexible element must comprise "a single molding." The parties agree that "comprises a single molding" means "formed from a single mold." Markman Order at 13. The Ultrasite piston component is molded as a single piece, which satisfies the claim limitation. Therefore, the Court finds that the Ultrasite valve literally infringes claim 5 of the '673 patent.

5. Claim 6 of the '673 patent

Claim 6 of the '673 patent incorporates all the limitations in claim 1 and adds that the valve must further comprise of "a rigid member positioned within the flexible element and to assist in maintaining the flexible element along an axial centerline when the flexible element moves between the uncompressed position and the compressed position." The rigid plug in the Ultrasite valve

satisfies this claim limitation. The rigid plug is made of a hard plastic, sits within the piston component, and prevents the piston assembly from bending when it is axially compressed. Braun contends that ICU undermines its infringement arguments regarding claim 1 because the piston component cannot be a "flexible element" if the rigid plug satisfies the "rigid member" limitation. This argument has already been rejected by the Court in its discussion of infringement of claim 1. Therefore, the Court finds that the unmodified Ultrasite valve literally infringes claim 6 of the '673 patent.

III. INFRINGEMENT OF THE '673 AND '204 PATENTS BY THE ULTRASITE VALVE WITH MODIFIED PISTON

*9 The '673 patent requires, among other things, a medical valve comprising a "flexible element" having at least three "external diameters," with "at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered." Similarly, the '204 patent requires a "resilient seal element" having "at least two generally arcuate segments" with "at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element." The claim limitation requiring different-sized maximum diameters was added during prosecution of the '204 patent, and ICU has asserted that this created a "taper" limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve contains a slight taper in the skirt of the piston component. Instead, it contends that the newly modified Ultrasite piston is straight-walled and cannot satisfy the "taper" limitation. In September and October of 2004, Braun modified the molds used to make the piston component to eliminate any mold draft. As a result, the modified piston component used in Ultrasite valves being manufactured today has straight walls. Braun has removed the alleged "taper" from the Ultrasite product, and now moves for summary judgment that the Ultrasite valve with modified piston does not infringe claims 1-6 of the '673 patent and claims 1-5 of the '204 patent.

A. Subject Matter Jurisdiction

Contrary to ICU's assertions, the Court has jurisdiction to decide Braun's summary judgment motion of non-infringement of the '673 and '204 patents by the Ultrasite valve with modified piston.

Under the Declaratory Judgment Act, a federal court may exercise jurisdiction over a matter only in "a case of actual controversy." 28 U.S.C. § 2201(a). The courts are forbidden from rendering advisory opinions. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed.Cir.1988). The test for determining whether an "actual controversy" exists involving patents is objective and two-pronged. First, an alleged infringer must have a reasonable apprehension that the patent holder will initiate suit if the party continues the allegedly infringing activity. Second, the alleged infringer must have either produced the device or have prepared to produce that device. *Id.* at 735-36.

Although subject matter jurisdiction is decided at the time of filing, once it has been established, a court may adjudicate all those claims and related defenses brought by the parties throughout the litigation as long as an "actual controversy" continues to exist. *See Preiser v. Newkirk*, 422 U.S. 395, 401, 95 S.Ct. 2330, 45 L.Ed.2d 272 (1975) ("The rule in federal cases is that an actual controversy must be extant at all stages of review, not merely at the time the complaint was filed"). For this reason, plaintiffs do not need to file a new action on the same patent for each modification made to an accused product during the course of litigation. Notably, the modified Ultrasite valve is not a new valve but a modification to one component of the same valve.

*10 The Court has jurisdiction over the newly modified Braun Ultrasite valve. In its Complaint, ICU generically alleges that Braun is infringing the '673 and '204 patents "by making, using, offering for sale, and selling within the United States Braun's *Ultrasite needleless medical connectors.*" First Amended Complaint at ¶ 7 (emphasis added). The newly-modified Ultrasite valve is essentially the same product ICU has accused of infringement in its Complaint, except the elastomeric piston component no longer has the non-functional mold draft that ICU alleges satisfies the "taper" limitation. In addition, ICU identifies in its Infringement Disclosures Braun's Ultrasite valve product family as "accused instrumentalities," including any future ones it may find in discovery: "ICU anticipates identifying additional infringing B.Braun Ultrasite Needle-Free Valve products after conducting discovery in this matter." [FN4] ICU's 3/31/04 Amended Initial Disclosure of Asserted Claims Under Patent L.R. 3-1.

> FN4. Further, ICU seeks damages on sales during the litigation and an injunction against future sales. These remedies cannot be decided without first determining whether the Ultrasite valves with modified piston infringe the '673 and '204 patents, because Braun does not make any more Ultrasite valves with unmodified pistons for sale in the United States.

Moreover, jurisdiction exists under Braun's declaratory counterclaim that its generic "Ultrasite needleless medical connectors" do not infringe the '673 patent. Braun's 3/5/04 Answer and Counterclaims at 12. An actual controversy existed at the time of filing because the parties were already in litigation over the Ultrasite valve product family, and Braun was making and selling the accused devices. *See* *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993) ("If ... a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim under the Act."). Braun's decision to modify the molds used to manufacture the piston component and remove the alleged "taper" in the piston skirt did not divest the court of its jurisdiction over Ultrasite needleless medical connectors.

Jurisdiction over the newly modified Ultrasite valve also exists because Braun had a reasonable apprehension that ICU would initiate suit because it was already litigating the action and ICU had not stipulated to non-infringement by the Ultrasite valve with modified piston. The evidence also shows that all the molds used to make pistons for Ultrasite products for sale in the United States were changed by October 2004, and valves with modified pistons were being commercially sold and used by customers. Even if Braun had only switched the molds but was not yet selling the modified valve to customers, an actual controversy still exists because Braun had prepared to produce the Ultrasite valve with modified piston. *See* *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed.Cir.1986) ("[T]he statutory requirement is satisfied when ... the plaintiff has 'actually produced the accused device' *or* has 'prepared to produce such a device.' ") (emphasis added).

It is not necessary for ICU to make any allegations regarding the redesigned product in order for the Court to have jurisdiction over the Ultrasite valve with modified piston. Jurisdiction existed when ICU filed the infringement action against generic Ultrasite valves, and continues to the present day. There is no heightened pleading standard for identifying specific modifications for accused products in infringement actions. *See* Fed.R.Civ.P. 9 (specifying the claims and defenses that require pleading with particularity).

***11** ICU's reliance on *Laitram Corp. v. Cambridge Wire Cloth Co.*, 919 F.2d 1579 (Fed.Cir.1990), is misplaced. Although the court in *Laitram* vacated summary judgment of non-infringement for lack of jurisdiction because the motion addressed products never accused of infringement, the facts are distinguishable from this case. There, the Federal Circuit was concerned with the *complete absence* of an accused product. *Laitram*, 919 F.2d at 1580 ("[T]he present record contains no evidence that any product accused of infringement had been made, used, or sold when the complaint was filed."). The only products before the district court when it granted summary judgment were the non-accused "possible constructions" of the product. *Id.* at 1581. Consequently, the Federal Circuit held that there was no true case or controversy. *Id.* ("In its motion, [plaintiff] was effectively and improperly saying to the district court, 'if we make and sell any of these four "possible constructions" please advise that we won't infringe.' Federal Courts do not sit, however, to decide hypotheticals or to issue advisory opinions."). In contrast, the accused Braun Ultrasite valves with modified piston are being made, used, and sold. Moreover, the Ultrasite valve with modified piston was not merely a "possible construction" of the product. By the end of 2004, Braun had modified the molds used to produce the piston component for all the Ultrasite valves manufactured and sold in the United States.

ICU also relies on *Field Container Co., L.P. v. Somerville Packaging Corp.*, 842 F.Supp. 338 (N.D.Ill.1994). The facts in *Field Container* are also inapposite to this case. There, the court found that the plaintiff in a declaratory judgment action failed to satisfy the burden of demonstrating an actual controversy. *Id.* at 342-43. A letter threatening legal action sent to the plaintiff could not establish a reasonable apprehension of suit because it referenced an older version of the product that was "significantly different" from the version then being produced by the plaintiff. *Id.* at 342 ("We are therefore unwilling to apply the transitive property and convert any 'reasonable apprehension of suit' with respect to Version 1 to a 'reasonable apprehension of suit' with

respect to Version 2."). Consequently, the court had no jurisdiction over the product at issue. In contrast, the difference between Braun's two Ultrasite valves is not substantial enough to bar a reasonable apprehension of suit with respect to the modified Ultrasite valve when ICU initiated its litigation against Braun's unmodified valve. Indeed, the two versions of the valve are almost identical. The mold draft on the piston component was a by-product of the manufacturing process, not a functional attribute of the product. Its removal did not alter the function or operation of the valve. Thus, it was reasonable for Braun to fear being sued for infringement if it manufactured the modified valve, particularly in light of ICU's refusal to stipulate to non-infringement by the Ultrasite valve with modified piston. Braun satisfied its burden to demonstrate that an actual controversy exists, and the Court has jurisdiction to consider whether the Ultrasite valve with modified piston infringes the '673 and '204 patents.

B. Non-Infringement

***12** The Court now turns to the merits of Braun's summary judgment motion with respect to the Ultrasite valve with modified piston. Both the '673 and '204 patents recite a medical valve containing a tapered structure. The parties agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21.

ICU asserts that the skirt of the piston component in Braun's Ultrasite valve satisfies this limitation. As to the Ultrasite valve with modified piston, Braun has now removed the alleged "taper" from the product. The piston skirt no longer gradually diminishes in width towards one end. Design drawings of the modified piston component show that the piston is no longer tapered. The piston skirt now consists of straight walls. Notably, even ICU does not contend that the modified Ultrasite product infringes (either literally or by virtue of the doctrine of equivalents) the '673 and '204 patents.

Thus, there is no genuine dispute that the modified Ultrasite valve does not infringe the '673 and '204 patents, and the Court grants Braun's motion for summary judgment of non-infringement by the Ultrasite valve with modified piston.

IV. INEQUITABLE CONDUCT

Braun has alleged in its pleadings that ICU's '673 patent is unenforceable because of the inequitable conduct of ICU during the prosecution of the '673 patent before the Patent and Trademark Office ("PTO").

Specifically, Braun argues that ICU committed inequitable conduct by failing to disclose the existence of this ongoing litigation and relevant litigation materials regarding infringement by the Ultrasite valve to the '673 patent examiner, while simultaneously prosecuting a new patent application with a petition alleging infringement by the same Ultrasite valve.

The '673 patent application was filed as a continuation of an abandoned application originally filed in December 1991. The inventor, Dr. George Lopez, [FN5] successfully petitioned for an expedited examination of the application based on the alleged infringement of the new invention by Braun's Ultrasite valve. The petition did not disclose that the assignee of the '673 patent, ICU, had already been in litigation with Braun over the same Ultrasite valve for over a year. It also failed to inform the PTO that ICU alleged in the ongoing litigation that the same Ultrasite valve infringed the '204 patent-a patent that shares the same specification as the '673 patent.

FN5. Dr. Lopez is also the inventor of the '204 patent and the Chief Executive Officer of plaintiff ICU Medical, Inc.

ICU, however, contends that there is no evidence of inequitable conduct on its part as to the prosecution of the '673 patent. ICU points out that the PTO was notified by the Clerk of the United States District Court for the Northern District of California as to the pending litigation involving the '048 and '673 patents pursuant to 35 U.S.C. § 290. Moreover, ICU disclosed all relevant prior art, including every prior art patent raised during the course of litigation,[FN6] to the PTO during the '673 prosecution in accordance with the applicable regulations. ICU argues that there is no evidence of any intent on its part to deceive or mislead the PTO.

FN6. The list of relevant prior art references raised during the course of litigation and disclosed by ICU to the PTO include: Armao (U.S. Patent No. 3,134,380), Adams (U.S. Patent No. 2,847,995), Vailancourt (U.S. Patent No. 4,512,766), DeFrank (U.S.

Patent No. 5,242,432), Cambio (U.S. Patent No. 4,201,208), and Lopez (U.S. Patent No. 4,782,841).

***13** The Court finds that the existence of this ongoing litigation was material to the '673 patent prosecution, and that ICU failed to disclose this information to the '673 patent examiner. There is also sufficient evidence to raise a genuine issue of triable fact as to whether ICU failed to disclose this ongoing litigation with the intent to mislead or deceive the PTO. Consequently, summary judgment in favor of ICU with respect to Braun's affirmative defense of inequitable conduct as to the '673 patent is not appropriate.

A. Applicable Law

A patent applicant's duty to disclose material information to the PTO arises under the general duty of candor, good faith, and honesty as set forth in 37 C.F.R. § 1.56(a), which states, in part:
Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

37 C.F.R. § 1.56(a).

The Manual of Patent Examining Procedure ("MPEP") further provides:
Where the *subject matter* for which a patent is being sought is or has been involved in litigation, *the existence of such litigation and any other material information arising therefrom* must be brought to the attention of the Patent and Trademark Office; such as, for example, evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of 'fraud,' 'inequitable conduct,' or violation of duty of disclosure. Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrogatories, deposition, and other documents, and testimony.

MPEP § 2001.06(c) (emphasis added). Although MPEP § 2001.6(c) is not binding law, it sheds light on the PTO's official interpretation of 37 C.F.R. § 1.56(a) regarding the materiality of related litigation.

A patentee commits inequitable conduct if, "during prosecution of the application, he makes an affirmative representation of material fact, fails to disclose material information, or submits false material information, and does so with intent to deceive." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed.Cir.2003) (citation omitted). To find inequitable conduct, there must be clear and convincing evidence that both the materiality and intent prongs of the test are satisfied. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed.Cir.2003).

1. Sufficiency of § 290 Notice

ICU contends that the ongoing litigation relating to infringement by the Ultrasite valve was properly disclosed and brought to the attention of the PTO when the Clerk gave notice of this litigation pursuant to 35 U.S.C. § 290. [FN7]

FN7. 35 U.S.C. § 290 provides:
The clerks of the courts of the United States, within one month after the filing of an action under this title shall give notice thereof in writing to the Director, setting forth so far as known the names and addresses of the parties, name of the inventor, and the designating number of the patent upon which the action has been brought.... The Director shall, on receipt of such notices, enter the same in the file of such patent.

The duties imposed by 37 C.F.R. § 1.56(a) and MPEP § 2001.06(c) cannot be supplanted by the general administrative notice required by Section 290. The patent applicant has an independent duty to disclose the existence of related patent infringement litigation to the PTO examiner. The duty of disclosure is particularly important in the context of patent prosecutions, which are conducted before an examiner in the absence of any represented adversary. In *ex parte* patent prosecutions, PTO examiners rely on the patent applicants to make full disclosure of material information of which they are aware in each case. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 147 (D.Mass.2001) ("[T]he duty of candor ultimately falls on the shoulders of the patent applicant...."). Moreover, the PTO has hundreds of examiners who handle hundreds of thousands of applications annually, and one examiner is unlikely to be aware of the status or assertions that an applicant makes to another examiner.

***14** Here, for example, although the Section 290 notice was sent to the PTO Director on the day the ongoing patent infringement action was filed, the PTO was directed under Section 290 to file the notice in the '204 and '048 patent file histories. Any Section 290 notice would not go to the examiner of the subsequent '673 patent application-a different, but related patent application. Indeed, the Section 290 notice appears nowhere in the '673 file history. As a result, the '673 patent examiner was unaware of this Court's claim constructions on similar language from the '204 and '048 patents. The '673 patent examiner was never told about Braun's invalidity contentions. The '673 patent examiner was never shown *any* of the pleadings or documents in this litigation. Consequently, ICU cannot rely on Section 290 to satisfy its duty to disclose the existence of related litigation to the '673 patent examiner.

In fact, the PTO advises that "the individuals covered by 37 C.F.R. 1.56 cannot assume that the examiner of a particular application is necessarily aware of other applications which are 'material to patentability' of the application in question, but must instead bring such other applications to the attention of the examiner." MPEP § 2001.6(b).[FN8] Likewise, an applicant cannot assume that an examiner, however diligent and well-informed, will be aware of Section 290 notices in other patents. To do so would effectively eviscerate the duty of disclosure regarding related litigation owed to each patent examiner.

> FN8. Furthermore, applicants should "continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive." *Critikon,* 120 F.3d at 1257.

2. Materiality

Information must be disclosed to the PTO when it is material to patentability. Materiality is not limited to prior art but includes "any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent. *Bristol-Myers,* 326 F.3d at 1234. According to the PTO, information is material to patentability if:
It is not cumulative to information already of record [in the application], and
(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
(2) It refutes, or is inconsistent with, a position the applicant [has taken] in:
(i) Opposing an argument of unpatentability relied on by the [PTO], or
(ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b).

In fact, related litigation is material *per se. See* MPEP § 2001.06(c) (stating that "the existence of such litigation *and any other* material arising therefrom" is material); *see also Daimlerc hrysler AG v. Fueling Advanced Techs., Inc.,* 276 F. Supp 2d 1054, 1063 (S.D.Cal.2003). Failure to disclose related litigation may lead to a finding of inequitable conduct. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.,* 120 F.3d 1253, 1255-59 (Fed.Cir.1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.,* 68 F.Supp.2d 508, 550-51 (D.N.J.1999) (denying patentee's preliminary-injunction motion because accused infringer had substantial defense of inequitable conduct based on patentee's failure to disclose materials from a related litigation to the examiner).

***15** The materiality of the '204 and '048 patent litigation which challenged both the validity and enforceability of the subject matter of the '673 application is obvious. Indeed, even ICU does not dispute that this ongoing litigation was material to the '673 patent prosecution. ICU Brief at 5-6. The '204 patent shared the same specification and disclosed the same subject matter as the '673 application. Braun also raised invalidity contentions against the patents-in-suit and alleged inequitable conduct against ICU in connection with its prosecution of the '048 patent, which may have been material to patentability of the '673 application. *See* MPEP § 2001.6(c) ("Examples of [ ]material information include ... allegations of 'fraud,' 'inequitable conduct,' and 'violation of duty of disclosure.' ").

3. Intent

As a general principle, the requirements of materiality and intent are inversely proportional. *See Critikon,* 120 F.3d at 1257. "A lesser quantum of intent is necessary when the omission or misrepresentation is highly material, and vice versa." *Diamlerchrysler,* 276 F.Supp.2d at 1065 (quoting

Amgen, 314 F.3d at 1358). Nevertheless, the intent to deceive or mislead cannot be inferred solely from the materiality of the omission. *Amgen*, 314 F.3d at 1358. Proof of intent to mislead may be shown by circumstantial evidence. *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1189-90 (Fed.Cir.1993) (" '[S]moking gun' evidence is not required in order to establish an intent to deceive.... Rather, this element of inequitable conduct, must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct.") (citation omitted).

A relatively high degree of intent may be demonstrated from the facts of this case. ICU was clearly aware that the subject matter of the pending litigation was material to the '673 patent prosecution. It knew that the claims of the '673 patent "read on" Braun's Ultrasite valve because it specifically alleged infringement by the Ultrasite valve in a Petition to Make Special to expedite examination of the '673 patent. Braun suggests that ICU's effort to obtain the '673 patent in time for use in this litigation provided a significant incentive for ICU to hide this litigation from the PTO examiner. [FN9]

> FN9. Indeed, disclosing the ongoing litigation may have forced ICU to address their various positions during litigation and consequently delayed the '673 patent prosecution by raising relevant invalidity defenses and material prior art.
> For example, the PTO examiner may have asked for more information regarding ICU's claim construction arguments that the '204 patent claims, which share the same specification as the '673 application, required a "taper" on the "resilient seal element" even if that term is never used. ICU relied on this "taper" limitation in opposing Braun's summary judgment motion for patent invalidity. Although the PTO examiner never had the opportunity to consider this information, ICU subsequently added an express "taper" limitation to the application claims of the '673 patent before it issued.

During the prosecution of the '673 application, ICU also objected to Braun's motion to compel production of pending ICU patent applications that were related to the '204 patent. ICU repeatedly told Magistrate Judge James that the applications were not "relevant," despite having already filed a Petition to Make Special alleging infringement by the same Ultrasite valve. This made it impossible for Braun to inform the '673 patent examiner of the pending litigation.

Put another way, ICU may have been trying to hide the pending litigation from the '673 patent examiner while simultaneously using the alleged infringement by the Ultrasite valve as a reason to expedite issuance of the '673 patent, which ICU could then use as a weapon in the ongoing litigation.

***16** ICU's reliance on *Haney v. Timesavers, Inc.*, 900 F.Supp. 1378, 1382 (D.Or.1995) (stating that "the court cannot infer an intent to deceive ... from the manner in which the information was conveyed to the Patent Office when the information was, in fact, conveyed.") is misplaced. In *Haney*, the district court found insufficient evidence to infer an intent to deceive and sustain an inequitable conduct claim. *Id.* Here, however, there is substantial evidence from which the Court could find that ICU had the intent to deceive the PTO regarding ongoing litigation surrounding the Ultrasite valve. ICU's failure to disclose the existence of this ongoing litigation regarding infringement by the Ultrasite valve to the '673 patent examiner, as well as the existence of the '673 application during discovery, while simultaneously prosecuting a new patent application with a petition alleging infringement by the same valve, raises a genuine issue of triable fact as to inequitable conduct.

CONCLUSION

For the reasons stated above, the Court hereby resolves the motions as follows:
1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

It is further ORDERED that trial on the issue of inequitable conduct shall begin on April 11, 2005 at

8:30 a.m. A pretrial conference shall be held on March 31, 2005 at 2:30 p.m.

IT IS SO ORDERED.

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